



541.1011CON

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Re: Application of: John N. STANIFORTH, et al.  
Serial No.: 10/015,538  
Examiner: BENNETT, Rachel M.  
Group No.: 1615  
Filed: December 13, 2001  
For: **A PROCESS FOR PREPARING A DIRECTLY  
COMPRESSIBLE SOLID DOSAGE FORM  
CONTAINING MICROCRYSTALLINE  
CELLULOSE**

**INFORMATION DISCLOSURE STATEMENT**

MAIL STOP: RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

November 26, 2003

Sir:

In accordance with the provisions of 37 C.F.R. § 1.97, Applicants hereby make of record the documents listed on the accompanying Form PTO-1449 for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the references cited are enclosed herewith.

It is respectfully requested that the references cited in the accompanying Form PTO-1449 be considered and made of record.

In accordance with the provisions of 37 C.F.R § 1.98 (d), copies of the references cited on pages 1-4 of the attached Form PTO-1449 are not enclosed herewith because these references have been previously submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 08/868,745, filed June 4, 1997 (now U.S. Patent No. 6,395,303).

Moreover, pursuant to 37 C.F.R § 1.98 (a) (2) (iii), a copy of the specification, pending claims and drawings for related Published U.S. Patent Application No. 2003/0099702, published May 29, 2003 and Published U.S. Patent Application No. 2003/0131957, published July 17, 2003, which are commonly assigned, are also enclosed. These pending applications are listed on page 5 of Form PTO-1449 as references EA-EB.

It should be noted that WO 9203126, corresponds to U.S. Patent No. 5,322,698. U.S. Patent No. 5, 322,698 (reference CH) and WO 9203126 (reference DL) are listed on the Form PTO 1449 and copies of each are attached thereto.

It should also be noted that DE 4303846 corresponds to U.S. Patent No. 5,560,926. Both DE 4303846 (reference DR) and U.S. Patent No.5,560,926 (reference DE) are listed on the Form PTO 1449 and copies of each are attached thereto.

Applicants also respectfully advise the Examiner of the following related U.S. patents and applications which are commonly assigned:

U.S. Patent Application No. 09/981,319, filed October 16, 2001; U.S. Patent Application No. 09/754,760, filed January 4, 2001 ( now U.S. Patent No. 6,358,533 B2); U.S. Patent Application No. 09/438,646, filed November 12, 1999 (now U.S. Patent No. 6,217,909); U.S. Patent Application No. 08/992,073, filed December 17, 1997 (now U.S. Patent No. 6,103,219); U.S. Patent Application No. 08/724,613, filed September 30, 1996 (now U.S. Patent No. 5,725,884); and U.S. Patent Application No. 08/370,576, January 9, 1995 (now U.S. Patent No.

5,585,115). It is noted that U.S. Patent Nos. 6,358,533; 6,217,909 and 6,103,219 are listed on page 5 of Form PTO 1449 as references EF-EH, respectively and copies of the specification and claims are enclosed herewith. It is further noted that U.S. Patent Nos. 5,725,884 and 5,585,115 are listed on page 4 of Form PTO 1449 as references DA and DC, respectively. As mentioned above, copies of these patents are not enclosed herewith because these patents were previously submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 08/868,745, filed June 4, 1997 (now U.S. Patent No. 6,395,303).

U.S. Patent Application No. 09/037,841, filed March 10, 1998 (now U.S. Patent No. 6,106,865); U.S. Patent Application No. 008/660,553, filed June 10, 1996 (now U.S. Patent No. 5,866,166); and U.S. Patent Application No. 08/486,183, filed June 7, 1995 (now U.S. Patent No. 5,725,883). It is noted that U.S. Patent Nos. 6,106,865 and 5,866,166 are listed on page 5 of Form PTO 1449 as references EI and EJ, respectively and copies of the specification and claims are enclosed herewith. It is further noted that U.S. Patent No. 5,725,883 is listed on page 4 of Form PTO 1449 as references DF. As mentioned above, a copy of this patent is not enclosed herewith because this patent was previously submitted to the United States Patent and Trademark Office in parent U.S. Patent Application No. 08/868,745, filed June 4, 1997 (now U.S. Patent No. 6,395,303).

It is respectfully submitted that the pending claims are patentable over all of the references made of record at this time.

This Information Disclosure Statement is being filed together with a Request for Continued Examination (RCE). Accordingly, a check in the amount of \$770.00 is enclosed for the RCE fee. It is believed that no additional fees are due at this time. However, if any additional fees are determined to be due or if any fees have been overpaid, the Commissioner for Patents is hereby authorized to charge said additional fees or credit any overpayment to Deposit Account No. 50-0552.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By



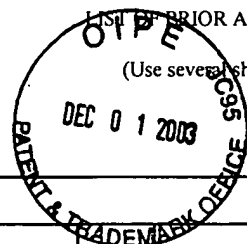
Cary S. Kappel

Reg. No. 36,561

Davidson, Davidson & Kappel, LLC  
485 Seventh Avenue, 14th Floor  
New York, New York 10018  
(212) 736-1940

FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: 541.1011CON		SERIAL NO.: 10/015 538								
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT(S): STANIFORTH, et al.		DEC 05 2003								
				FILING DATE: 12/13/01		GROUP: 1615 TECH CENTER 1600/2900								
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	AA	H	1	2	2	9	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE			
	AB	3	0	2	3	1	0	4	2/27/62	Battista, et al.	99	1		
	AC	3	0	6	7	0	3	7	12/4/62	Herald, et al.	99	139		
	AD	3	1	4	1	8	7	5	7/21/64	Battista, et al.	260	212		
	AE	3	5	3	9	3	6	5	11/10/70	Durand, et al.	CO8b	21/30		
	AF	3	5	7	3	0	5	8	3/30/71	Tiemstra, et al.	A231	1/00		
	AG	4	1	0	9	0	1	8	8/22/78	Thompson	A21D	2/36		
	AH	4	1	4	3	1	6	3	3/6/79	Hutchison, et al.	A23L	1/04		
	AI	4	1	5	6	0	2	1	5/22/79	Richardson	A23D	5/00		
	AJ	4	1	5	9	3	4	5	6/26/79	Takeo, et al.	A61K	47/00		
	AK	4	2	1	9	5	8	0	8/26/80	Torres	A21D	2/18		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	AL	WO	90	1	4	0	1	7	11/29/90	PCT	A23L	1/0534	N/A	
	AM	WO	92	1	2	6	3	3	8/6/92	PCT	A01N	25/10	N/A	
	AN	WO	93	1	2	7	6	8	7/8/93	PCT	A61K	9/14	N/A	
	AO	WO	94	0	6	3	0	9	3/31/94	PCT	A23L	1/38	N/A	
	AP	WO	95	2	0	3	2	6	8/3/95	PCT	A23L	1/0534	N/A	
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)														
	AR	Machines Collette High Shear Mixer Granulator Promotional Literature (date unknown)												
	AS													
	AT													
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

RECEIVED



FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE  
LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.:  
541.1011CON

SERIAL NO.: 10/013133

APPLICANT(S): STANIFORTH, et al.

FILING DATE: 12/31/01

GROUP: 1615

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BA	4	2	3	2	0	5	2	11/4/80	Nappen	A23D	5/00	
	BB												
	BC	4	6	6	4	9	1	5	5/12/87	Simonian	A61K	31/61	
	BD	4	7	2	1	7	0	9	1/26/88	Seth, et al.	A61K	31/55	
	BE	4	7	4	4	9	8	7	5/17/88	Mehra, et al.	A61K	9/14	
	BF	4	7	4	8	0	2	7	5/31/88	Schou, et al.	A23L	1/035	
	BG	4	8	1	4	1	9	5	3/21/89	Yokoyama, et al.	A23L	1/38	
	BH	4	8	4	9	2	2	7	1/18/89	Cho	A61K	9/16	
	BI												
	BJ	4	9	1	1	9	4	6	3/27/90	Singer, et al.	A23D	3/00	
	BK	4	9	2	3	9	8	1	5/8/90	Weibel, et al.	A61K	47/00	
	BL	4	9	4	6	6	8	5	8/7/90	Edgren, et al.	A61K	9/24	
	BM	4	9	8	0	1	9	3	12/25/90	Tuason, Jr., et al.	A23L	1/522	
	BN	5	0	1	1	7	0	1	4/30/91	Baer, et al.	A23L	0/534	
	BO	5	0	1	9	3	9	7	5/28/91	Wong, et al.	A61K	9/24	
	BP	5	0	2	6	5	6	9	6/25/91	Forand	A21D	13/04	

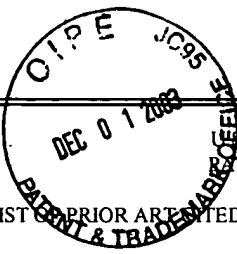
## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	BQ	1	2	6	1	2	6	1	9/2689	Canada	A61K	9/20	N/A	
	BR	0	6	0	9	9	7	6	01/04/94	EP (A1)	CO8B	15/02	N/A	

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	BS	
EXAMINER	DATE CONSIDERED	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



RECEIVED

DEC 05 2003

TECH CENTER 1600/2900

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
541.1011CON

SERIAL NO.: 10/015,538

LIST OF PRIOR ART CITED BY APPLICANT

(Use several sheets if necessary)

APPLICANT(S): STANIFORTH, et al.

FILING DATE: 12/31/01

GROUP: 1615

## U.S. PATENT DOCUMENTS

TECH CENTER 1600/2900

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	CA	5	0	3	0	4	0	0	7/9/91	Danielsen, et al.	B29B	9/08	
	CB	5	0	7	5	1	1	5	12/24/91	Brine	A61K	9/14	
	CC	5	1	2	6	1	4	5	6/30/92	Evenstad, et al.	A61K	9/20	
	CD	5	1	3	2	1	2	8	7/21/92	Rockland	A23G	3/00	
	CE	5	1	5	8	7	9	8	10/27/92	Fung, et al.	A23D	9/00	
	CF	5	1	9	2	5	6	9	3/9/93	McGinley, et al.	A23L	1/0526	
	CG	5	2	0	9	9	4	2	5/11/93	Bauer, et al.	A23C	1/24	
	CH	5	3	2	2	6	9	8	6/21/94	Kovács, et al.	A61K	9/36	
	CI	5	3	3	8	5	6	2	8/16/94	Humphreys	A23D	9/04	
	CJ	5	3	6	6	7	4	2	11/22/94	Tauson, Jr., et al.	A23L	1/0532	
	CK	5	4	2	9	8	3	0	7/4/95	Janovsky, et al.	A23G	3/00	
	CL	5	4	4	1	7	3	1	8/15/95	Jaxa-Chamiec, et al.	A61K	31/74	
	CM	5	4	4	1	7	5	3	8/15/95	McGinley, et al.	A23L	1/0534	
	CN	5	4	4	7	7	2	9	9/5/95	Belenduik, et al.	A61K	9/16	
	CO												
	CP	5	4	6	2	7	6	1	10/31/95	McGinley, et al.	A23L	1/0528	
	CQ	5	5	0	5	9	8	2	4/9/96	Krawczyk, et al.	A23L	1/0534	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	CR	0	4	3	0	2	8	7	6/5/91	EP (A2)	A61K	9/52	N/A	

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CS	
EXAMINER	DATE CONSIDERED	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
541.1011CON

SERIAL NO.: 10/015,538

LIST OF PRIOR ART CITED BY APPLICANT

APPLICANT(S): STANIFORTH, et al.

(Use several sheets if necessary)

FILING DATE: 12/13/01

GROUP: 1615

## U.S. PATENT DOCUMENTS

TECH CENTER 1600/2900

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	DA	5	5	8	5	1	1	5	12/17/96	Sherwood, et al.	A61K	9/14	
	DB	5	7	4	1	5	2	4	4/21/98	Staniforth, et al.	A61K	9/14	
	DC	5	7	2	5	8	8	4	3/10/98	Sherwood, et al.	A61K	9/14	
	DD	4	5	3	3	6	7	4	8/6/85	Schmidt, et al.	514	474	
	DE	5	5	6	0	9	2	6	10/1/96	Franz, et al.	424	464	
	DF	5	7	2	5	8	8	3	3/10/98	Staniforth, et al.	424	489	
	DG	5	8	5	8	4	1	2	1/12/99	Staniforth	A61K	9/14	
	DH	5	7	3	3	5	7	8	3/31/98	Hunter, et al.	424	489	
	DI	5	8	5	8	4	0	9	1/12/99	Karetny, et al.	A61K	9/14	
	DJ												
	DK												

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	DL	WO	92	0	3	1	2	6	3/5/92	PCT	A61K	9/20	N/A	
	DM	0	5	4	3	5	4	1	5/26/93	EP (A1)	A61K	31/165	N/A	
	DN	1	4	6	4	2	0	0	2/9/77	GB	A61K	31/505	N/A	
	DO	0	3	0	5	0	5	1	3/1/8/9	EP (A1)	A61K	9/22	N/A	
	DP	1	4	8	0	1	8	8	7/20/77	GB	A61K	9/16	N/A	
	DQ	WO	95	3	5	1	0	4	12/28/95	PCT	A61K	31/19	N/A	
	DR	4	3	0	3	8	4	6	8/11/94	DE	A61K	31/19		X

## OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

DQ

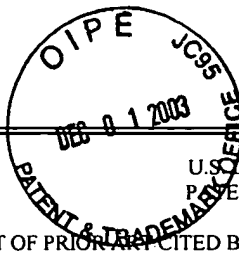
EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO.: 541.1011CON		SERIAL NO.: 10/015,538						
LIST OF PRIOR ART CITED BY APPLICANT (Use several sheets if necessary)						APPLICANT(S): STANIFORTH, et al.								
						FILING DATE: 12/13/01		GROUP: 1615						
U.S. PATENT DOCUMENTS														
*EXAMINER INITIAL	EA	20	03	00	99	7	0	2	5/29/03	Staniforth, et al.	424	465	FILING DATE IF APPROPRIATE	
	EB	20	03	00	96	0	0	5	5/22/03	Sherwood, et al.	424	465		
	EC	20	03	02	06	9	7	8	11/6/03	Sherwood, et al.	424	728		
	ED	20	03	02	03	0	5	0	10/30/03	Sherwood, et al.	424	725		
	EE	20	03	00	86	9	8	2	5/8/03	Sherwood, et al.	424	725		
	EF	6	3	5	8	5	3	3	3/19/02	Sherwood, et al.	424	494		
	EG	6	2	1	7	9	0	9	4/17/01	Sherwood, et al.	424	494		
	EH	6	1	0	3	2	1	9	8/15/00	Sherwood, et al.	424	49		
	EI	6	1	0	6	8	6	5	8/22/00	Staniforth, et al.	424	489		
	EJ	5	8	6	6	1	6	6	2/2/99	Staniforth, et al.	424	489		
	EK	6	5	2	1	2	6	1	2/18/03	Sherwood, et al.	424	494		
	EL	20	03	01	04	0	7	6	6/5/03	Wilhelm, et al.	424	725		
FOREIGN PATENT DOCUMENTS														
		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
													YES	NO
	EM	WO	99	1	5	1	5	5	4/1/99	PCT	A61K	9/20	N/A	
	EN	0	6	0	9	9	7	6	8/10/94	EP	C08B	15/02	N/A	
	EO	0	6	1	7	1	9	1	9/28/94	EP			Abstract	
EXAMINER										DATE CONSIDERED				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.														

FORM PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.:  
541.1011CON

SERIAL NO.: 10/011,238

RECEIVED

LIST OF PRIOR ART CITED BY APPLICANT

APPLICANT(S): STANIFORTH, et al.

DEC 05 2003

(Use several sheets if necessary)

FILING DATE: 12/31/01

GROUP: 1615

TECH CENTER 1600/2900

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	FA	6	4	7	1	9	9	4	10/29/02	Staniforth, et al.	424	489	
	FB	6	4	4	7	8	1	5	9/10/02	Menon, et al.	424	737	
	FC	6	3	9	5	3	0	3	5/28/02	Staniforth, et al.	424	499	
	FD	6	3	9	1	3	3	7	5/21/02	Hunter, et al.	424	474	
	FE	6	3	8	3	5	2	6	5/7/02	Andrews, et al.	424	733	
	FF	6	2	1	7	9	0	7	4/17/01	Hunter, et al.	424	489	
	FG	6	1	9	0	6	9	6	2/20/01	Groenewoud	424	464	
	FH	6	1	5	3	2	2	0	11/28/00	Cumming, et al.	424	464	
	FI	6	0	3	0	6	4	5	2/29/00	Tritsch, et al.	424	490	
	FJ	5	9	6	5	1	6	6	10/12/99	Hunter, et al.	424	489	
	FK	5	9	4	8	4	3	8	9/7/99	Staniforth, et al.	424	464	
	FL	5	7	9	8	1	0	1	8/25/98	Haveson	424	195.1	
	FM	5	7	0	9	8	8	0	1/20/98	Del Corral, et al.	424	464	
	FN	5	4	6	6	4	5	2	11/14/95	Whittle	424	195.1	
	FO	5	4	6	2	7	4	7	10/31/95	Radebaugh, et al.	424	465	
	FP	4	9	1	0	0	2	3	3/20/90	Botzolakis, et al.	424	470	
	FQ	4	8	1	0	5	1	6	3/7/89	Kong-Chan	426	548	
	FR	4	5	3	6	5	1	1	8/20/85	Fischer, et al.	514	404	
	FS	4	5	1	9	9	6	1	5/28/85	Schumacher, et al.	264	4.6	
	FT	4	3	9	5	4	9	1	7/26/83	Hohl, et al.	435	262	
	FU	2	7	5	6	1	7	7	7/24/56	Cannalunga, et al.	167	81	

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.